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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,981

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272 7590 07/31/2009  
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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT

PAPER NUMBER

1794

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,981	<b>Applicant(s)</b> JEMELIN, VINCENT	
	<b>Examiner</b> WALTER B. AUGHENBAUGH	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10, 11 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 11 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 26, 2009 has been entered.

### ***Acknowledgement of Applicant's Amendments***

2. Applicant's cancellation of claim 14 has been acknowledged by Examiner.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the subject matter that Applicant intends to delineate in claim 10 cannot be ascertained due to the recitation "the capsule is formed exclusively of cyclic olefin copolymer". The recitation "the capsule is formed exclusively of cyclic olefin copolymer" does not clearly indicate whether Applicant intends to recite that the capsule comprises cyclic olefin copolymer, consists of cyclic olefin copolymer, or consists essentially of cyclic olefin copolymer. Clarification and/or correction (replacement of "is formed exclusively of" with one of the conventional transitional phrase indicators) is required.

***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berghahn (USPN 3,757,979) in view of Sudo et al. (USPN 5,853,833).

Berghahn teach a safety closure-bottle assembly for medicine that comprises a capsule (bottle 5 of Berghahn) and a cap (safety closure 3 of Berghahn) (see, for example, Figures and col. 1, lines 3-8). Berghahn teach that the cap is formed of low density polyethylene (col. 6, lines 20-30). The recitation “for holding a dental implant with a fluid material preserving the dental implant” is an intended use phrase that has not been given patentable weight, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from a prior art article satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQd 1647 (1987). There is no indication in Berghahn that the bottle is anything other than a monolayer bottle (see, for example, Fig. 8). Even if the bottle of Berghahn were a multilayer bottle (there is no indication of this in Berghahn), a single layer of this hypothetical multilayer bottle would correspond to the recited “capsule” (note that the “capsule” is recited as a component of the “package”).

Berghahn fails to teach that the capsule is formed exclusively of cyclic olefin copolymer with an impermeability to moisture of less than 5% fluid loss per year. Berghahn fails to teach that the capsule is formed exclusively of cyclic olefin copolymer because Berghahn does not specifically teach cyclic olefin copolymer.

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Sudo et al. (USPN 5,853,833), however, disclose a sanitary container for medicine (see, for example, col. 6, lines 32-34 and col. 1, lines 5-15) formed exclusively of cyclic olefin copolymer (see, for example, col. 3, lines 40-49), and that the cyclic olefin copolymer enables the contents of the container to be stably and sanitarilly stored (col. 1, lines 5-15 and col. 2, lines 51-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the bottle 5 of Berghahn exclusively out of the cyclic olefin copolymer disclosed by Sudo et al. since cyclic olefin copolymer is known to be a polymeric material for containers of medical products that enables the contents of the container to be stably and sanitarilly stored as taught by Sudo et al.

In regard to the recitation that the cyclic olefin copolymer has an impermeability to moisture of less than 5% fluid loss per year, the container taught by Berghahn and Sudo et al. meets the limitation regarding the maximum fluid loss per year because Berghahn and Sudo et al. teach all of the claimed structural and compositional limitations. Note also that Applicant's specification discloses that the "fluid loss per year" of cyclic olefin copolymer is "less than 5%"; and that this statement is not limited to any particular cyclic olefin copolymer of Applicant's invention, but rather is made generally in regard to cyclic olefin copolymer (which Applicant's specification describes as having "an excellent impermeability to moisture": cyclic olefin copolymer has "an excellent impermeability to moisture", Applicant's specification does not disclose any particular aspect of Applicant's invention that results in cyclic olefin copolymer having the recited "fluid loss per year"). See paragraph 0020 of Applicant's specification (page 4, lines 16-22).

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In regard to claim 11, Berghahn and Sudo et al. teach the package as discussed above in regard to claim 10.

Berghahn fails to explicitly teach that the package includes a barrier sealing the capsule.

Sudo et al. (USPN 5,853,833), however, disclose that the sanitary container may include a silicon oxide coating applied to the surface of the cyclic olefin container (see, for example, col. 9, lines 10-17) that improves the transmission resistance to oxygen and nitrogen of the cyclic olefin container (see, for example, col. 3, lines 5-19). This silicon oxide coating corresponds to the barrier sealing the capsule claimed in claim 11.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the capsule of the package taught by Berghahn and Sudo et al. with the silicon oxide coating of Sudo et al. in order to improve the transmission resistance to oxygen and nitrogen of the cyclic olefin container of Sudo as taught by Sudo et al.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berghahn (USPN 3,757,979) in view of Sudo et al. (USPN 5,853,833) and in further view of Sudo (USPN 5,723,189).

Berghahn and Sudo et al. teach the package as discussed above in regard to claim 10.

Berghahn and Sudo et al. fail to explicitly teach an ampoule within the capsule, where the ampoule is formed of cyclic olefin copolymer.

Sudo (USPN 5,723,189), however, discloses that it is well known in the art that ampoules containing liquid medicament are enclosed in a container (col. 1, lines 64-66) in order to maintain the sanitary nature of the medicament during storage of the medicament in a container

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(col. 1, lines 9-17) and that the cyclic olefin copolymer is suitable for use as any of a multiplicity of containers such as cases, sacks, vials, press through packs, slip pouches, partitioned vessels, ampoules “and the like) (col. 12, lines 28-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have stored ampoules in the capsule taught by Berghahn and Sudo et al. since it is well known in the art that ampoules containing liquid medicament are enclosed in a container in order to maintain the sanitary nature of the medicament during storage of the medicament in a container as taught by Sudo, and to have used cyclic olefin copolymer as the material of the ampoules since cyclic olefin copolymer is a suitable material for use as the material of ampoule used to store medicament as taught by Sudo et al. ‘833 (and as also taught by Sudo ‘189).

### ***Response to Arguments***

8. Applicant’s arguments presented in the Amendment filed May 26, 2009 in regard to the 35 U.S.C. 103 rejections of the claims have been fully considered but are not persuasive.

Berghahn (USPN 3,757,979) and Sudo et al. (USPN 5,853,833) teach the claimed article for the reasons of record in the updated rejection made of record in this Office Action.

In response to Applicant’s statements in the first paragraph on page 4 of the Amendment filed May 26, 2009, Berghahn fails to teach that the capsule is formed exclusively of cyclic olefin copolymer because Berghahn does not specifically teach cyclic olefin copolymer. If Berghahn does not teach cyclic olefin copolymer, Berghahn cannot teach that the capsule is formed exclusively of cyclic olefin copolymer. As explained in the rejection of record above, however, Berghahn does teach a monolayer capsule.

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Applicant states that “Bergahn only discloses... that “this case bottle 5 was molded of high density polyethylene...”, and argues that there is no “hint” that the bottle “is formed exclusively of” high density polyethylene. However, the fact that Bergahn “only discloses” high density polyethylene (and that this disclosure is made “in a general and open-ended manner” as described by Applicant) weighs in favor of a teaching that the bottle “is formed exclusively of” high density polyethylene. It is also not clear what Applicant intends to state by “in a general and open-ended manner”. Clarification is requested.

Also see the 35 U.S.C. 112, second paragraph, rejection of claim 10 in regard to the phrase “the capsule is formed exclusively of cyclic olefin copolymer”.

Applicant argues that the proposed combination of references does not teach a capsule that “is formed exclusively of cyclic olefin copolymer” because the secondary reference Sudo requires an inorganic coating along with the cyclic olefin copolymer layer. However, the primary reference Berghahn does not require an inorganic layer, and Sudo is relied upon for its teaching of cyclic olefin copolymer layer as a suitable polymeric material for a container for the stable and sanitary storage of medicine.

The relevance of Applicant's statements starting at the paragraph bridging pages 4 and 5 through the paragraph bridging pages 5 and 6 to the rejection of record in the Final Rejection (and to the current, updated rejection) cannot be ascertained. Clarification is requested. For example, Applicant argues that Berghahn uses different materials for the capsule (bottle) and the closure, but so does Applicant's claimed invention. See claim 10. Clarification is requested.

Both containers of Berghahn and Sudo et al. are containers for storing medicine, and therefore are analogous (and therefore combinable) references.



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In regard to the recitation that the cyclic olefin copolymer has an impermeability to moisture of less than 5% fluid loss per year, the container taught by Berghahn and Sudo et al. meets the limitation regarding the maximum fluid loss per year because Berghahn and Sudo et al. teach all of the claimed structural and compositional limitations. Note also that Applicant's specification discloses that the "fluid loss per year" of cyclic olefin copolymer is "less than 5%"; and that this statement is not limited to any particular cyclic olefin copolymer of Applicant's invention, but rather is made generally in regard to cyclic olefin copolymer (which Applicant's specification describes as having "an excellent impermeability to moisture": cyclic olefin copolymer has "an excellent impermeability to moisture", Applicant's specification does not disclose any particular aspect of Applicant's invention that results in cyclic olefin copolymer having the recited "fluid loss per year"). See paragraph 0020 of Applicant's specification (page 4, lines 16-22).

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 7:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye, can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Walter B Aughenbaugh /

Examiner, Art Unit 1794

7/29/09